

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---------------|--------------------|---|------------------|---------------|
| Applicant(s): | Steer et al. |) | Group Art Unit: | 1649 |
| | |) | | |
| Serial No.: | 10/549,867 |) | Examiner: | Chang Yu Wang |
| | |) | | |
| Filed: | September 22, 2005 |) | Confirmation No. | 4764 |
| | |) | | |

For: METHODS FOR PROMOTING CELL VIABILITY

DECLARATION UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

We, Walter C. Low and Clifford J. Steer, declare and say as follows:

1. We are co-inventors of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 10/549,867, filed September 22, 2005, which is a U.S. National Stage Application of International Application PCT/US2003/09819, filed April 2, 2003.
2. One of us, Walter C. Low, received a Ph.D. from the University of Michigan in Ann Arbor in 1979 and a B.S. degree from the University of California at Santa Barbara. At the time of the invention I was a Professor in the Department of Neurosurgery and Director of the Neurosurgery Research Laboratories at the University of Minnesota.
3. One of us, Clifford John Steer, received a M.D. from the University of Minnesota, School of Medicine, in 1974 and a B.A. in Physiology and Chemistry from the University of Minnesota, College of Liberal Arts, in 1970. At the time of the invention I was a Professor in the Departments of Medicine and Genetics, Cell Biology, and Development and the Director of the Molecular Gastroenterology Program at the University of Minnesota.
4. We have read and are familiar with the Office Action mailed July 17, 2009, with respect to the above-identified application and with Duan et al., "Tauroursodeoxycholic Acid Improves the Survival and Function of Nigral Transplants in a Rat Model of Parkinson's

Disease," 2002, *Cell Transplantation*; 11(3):195-205 (hereinafter referred to as Duan et al.), a publication having been cited by the Examiner in the July 17, 2009, Office Action, and make this Declaration in support of the patentability of the claims of application Serial No. 10/549,867.

5. That we (Walter C. Low and Clifford J. Steer) are among the co-authors of the above-referenced Duan et al. publication and that the other authors of this publication, i.e., Wei-Ming Duan, Cecilia M.P. Rodrigues, and Li-Ru Zhao, are not co-inventors of the above-identified U.S. patent Application Serial No. 10/549,867.

6. That at the time the research was carried out that led to the Duan et al. publication, Wei-Ming Duan was a postdoctoral fellow in the laboratory of one of us (Walter C. Low) in the Department of Neurosurgery at the University of Minnesota, that Wei-Ming Duan worked under his close supervision and direction, and that Wei-Ming Duan did not make independent intellectual and original contributions to the research.

7. That at the time the research was carried out that led to the Duan et al. publication, Cecilia M.P. Rodrigues was an Assistant Professor in the Research Institute for Medicines and Pharmaceutical Sciences, Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal, and a visiting postdoctoral fellow in the laboratory of one of us (Clifford J. Steer) in the Departments of Medicine and Genetics, Cell Biology, and Development at the University of Minnesota, that Cecilia M.P. Rodrigues worked under his supervision and direction, providing technical assistance with various experimental techniques used in the research that led to the Duan et al. publication, including cell culture and assessment, immunocytochemistry, TH assay, and TUNEL assay, and that Cecilia M.P. Rodrigues did not make independent intellectual and original contributions to the research.

8. That at the time the research was carried out that led to the Duan et al. publication, Li-Ru Zhao was a postdoctoral fellow in the laboratory of one of us (Walter C. Low) in the Department of Neurosurgery at the University of Minnesota, that Li-Ru Zhao worked under his close supervision and direction, and that Li-Ru Zhao did not make independent intellectual and original contributions to the research.

9. That we, Walter C. Low and Clifford J. Steer, are co-inventors of the subject matter that is commonly disclosed in the Duan et al. publication and in the above-identified U.S. Patent Application Serial No. 10/549,867.

10. We further declare that statements made herein of our knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: Jan. 19, 2010

By: Walter C. Low
Walter C. Low

Dated: _____

By: _____
Clifford J. Steer

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8. That at the time the research was carried out that led to the Duan et al. publication, Li-Ru Zhao was a postdoctoral fellow in the laboratory of one of us (Walter C. Low) in the Department of Neurosurgery at the University of Minnesota, that Li-Ru Zhao worked under his close supervision and direction, and that Li-Ru Zhao did not make independent intellectual and original contributions to the research.

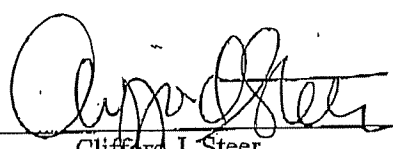
9. That we, Walter C. Low and Clifford J. Steer, are co-inventors of the subject matter that is commonly disclosed in the Duan et al. publication and in the above-identified U.S. Patent Application Serial No. 10/549,867.

10. We further declare that statements made herein of our knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: _____

By: _____
Walter C. Low

Dated: 01/18/2010

By:  _____
Clifford J. Steer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| For: | METHODS OF PROMOTING CELL VIABILITY | | | |

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Assistant Commissioner for Patents
Washington D.C. 20231

Dear Sir:

I, Margaret S. Willis, declare and say as follows:

1. I am a technical specialist employed by Muetting, Raasch & Gebhardt, P.A., Minneapolis, Minnesota.

2. To determine the date on which the Duan et al. publication "Tauroursodeoxycholic Acid Improves the Survival and Function of Nigral Transplants in a Rat Model of Parkinson's Disease," *Cell Transplantation*, 2002;11(3):195-205 was first made publically available, I contacted Cognizant Communication Corporation, the publisher of *Cell Transplantation*, at (914) 592-7720. On December 28, 2009, I spoke with Lori Miranda of Cognizant Communication Corporation. The article entitled "Tauroursodeoxycholic Acid Improves the Survival and Function of Nigral Transplants in a Rat Model of Parkinson's Disease" by Duan et al. was published in Volume 11, No. 3 of *Cell Transplantation* on pages 195-205 (2002). Ms. Miranda informed me that Volume 11, No. 3 of *Cell Transplantation* was published and released to the public on June 7, 2002.

Declaration under 37 CFR §1.132

Page 2 of 2

Serial No.: 10/549,867

Confirmation No.: 4764

Filed: September 22, 2005

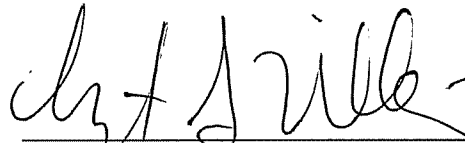
For: METHODS OF PROMOTING CELL VIABILITY

3. Upon information and belief, I hereby state that publication Duan et al., "Tauroursodeoxycholic Acid Improves the Survival and Function of Nigral Transplants in a Rat Model of Parkinson's Disease," *Cell Transplantation*, 2002;11(3):195-205 first became publically available on June 7, 2002.

4. I further declare that statements made herein of our knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1/18/2010

Date



Margaret S. Willis